POM Wonderful: Implications for FTC and FDA Substantiation Requirements

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On January 30, 2015 the D.C. Circuit issued a decision in POM Wonderful, LLC v. FTC, no. 13-1060, largely upholding an order by the Federal Trade Commission (FTC) that pomegranate juice manufacturer POM Wonderful (POM) cannot advertise that its products treat or prevent diseases unless it has adequate scientific evidence. But, the Court ruled, FTC failed to justify its requirement that POM have at least two randomized and controlled human clinical trials (RCTs) as a precondition for making any such claim.

FTC shares jurisdiction with the Food and Drug Administration (FDA) over the promotion of foods, drugs, devices, and cosmetics. Under the Federal Trade Commission Act (FTCA), advertising and promotional materials must be truthful, non-misleading, and substantiated.[1] The FTCA requires that advertisers have reasonable bases for product claims. What constitutes a reasonable basis depends on the type of product being advertised, the type of claim being made, and what experts in the relevant field would consider adequate to establish the truthfulness of the claim. Thus, FTC traditionally has required health-related claims to be supported by competent and reliable scientific evidence. The POM case was about the type and quantity of evidence POM needed to satisfy that standard.

POM sells pomegranate-based products, including juice and two dietary supplements of concentrated pomegranate extract, POM$_x$ Pills and POM$_x$ Liquid. Between 2003 and 2010, POM's advertisements included claims that its products could treat or prevent various ailments, including heart disease, prostate cancer, and erectile dysfunction. According to the D.C. Circuit, POM's promotional materials "regularly reference scientific support" for the claims, without noting study limitations or contrary findings.[2] For example, a 2007 brochure by POM featured a physician statement that "POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health" and a description of a supporting study—but made no mention of contrary findings from two other studies examining whether POM products improve cardiovascular health.

[1] FTC Act § 5(a)(1); FTC Act § 12(a).

[2] POM Wonderful, LLC v. FTC, no. 13-1060, at *4, *8.

In 2010, FTC issued an administrative complaint identifying forty-three of POM's ads as false, misleading, or unsubstantiated in violation of the FTCA.[3] After a lengthy administrative trial, an administrative law judge found that nineteen of POM's ads contained misleading, unsubstantiated disease claims and ordered POM to cease and desist from making further such claims without competent and reliable scientific evidence.[4]

On appeal, the full Commission affirmed. First, FTC determined POM's ads conveyed material claims that its products treat, prevent, or reduce the risk of disease. Further, FTC found that POM's disclaimers or disclosures generally did not alter the positive "net impression" of the ad.[5] The Commission noted, however, that it might have reached a different result with a stronger disclaimer such as "evidence in support of this claim is inconclusive."[6] Second, FTC found that without the support of evidence from randomized and controlled human clinical trials, POM's claims were inadequately substantiated and thus deceptive. FTC distinguished "generalized nutritional and health benefit claims" from disease-specific claims, which require more stringent supporting evidence.[7]

Accordingly, FTC issued an injunctive order against POM prohibiting POM from making disease claims unless they were non-misleading and supported by "competent and reliable scientific evidence that, when considered in light of the entire body of relevant and reliable scientific evidence, is sufficient to substantiate that the representation is true."[8] The order defined competent and reliable scientific evidence as "at least two randomized and controlled human clinical trials (RCTs) that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies" and also yielding significant results and double-blinded (if possible).[9]

POM appealed to the D.C. Circuit, maintaining that it did have sufficient evidence for its claims, but that it was unnecessary—and practically impossible—to meet FTC's standard and that the standard violated POM's First Amendment rights.[10] FTC's findings on appeal are entitled to a deferential

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[3] Id. at *12.

[4] Id.

[5] Id. at *21.

[6] Id.

[7] Id. at *23.

[8] Id. at *13.

[9] Id. at *14.

[10] Id. at *27.

standard of review. That standard "does not permit the reviewing court to weigh the evidence, but only to determine that there is in the record such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[11] The Court defers to FTC because it "is often in a better position…to determine when a practice is 'deceptive.'"[12] Under that standard, the D.C. Circuit upheld FTC's factual findings, concluding that the evidence supported FTC's finding that the ads were not substantiated.[13]

The Court criticized POM for relying on positive studies, while ignoring significant negative or inconclusive studies. In short, the Court concluded that "[m]any of [POM's] ads mischaracterized the scientific evidence concerning the health benefits of POM's products with regard to those diseases" because they failed to consider the entire body of the evidence before it.[14] POM's use of qualifiers such as "promising," "initial," and "preliminary" did not alter this finding.[15] But the D.C. Circuit left open the possibility that an appropriate and substantive disclaimer of the limits of the studies might sufficiently qualify the claim.[16] The Court explained: "An advertiser . . . may assert a health-related claim backed by medical evidence falling short of an RCT if it includes an effective disclaimer disclosing the limitations of the supporting research."[17]

The Court rejected POM's argument that it is "'too onerous' to require RCTs to substantiate disease-related claims about food products 'because of practical, ethical, and economic constraints on RCT testing in that context.'"[18] The Court was unsympathetic to POM's position, noting the inconsistency in POM's position in light of the millions of dollars it had spent sponsoring studies.[19] The Court went on to state that "if the cost of an RCT proves prohibitive, petitioners can choose to specify a lower level of substantiation for their claims."[20]

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[11] Id. at *27.

[12] Id. at *15.

[13] Id. at *3.

[14] Id. at *2.

[15] Id. at *21.

[16] Id.

[17] Id. at *29.

[18] Id. at *27.

[19] Id. at *28–29.

[20] Id. at *29.

Next, the Court undertook an analysis of POM's First Amendment arguments. The Court rejected POM's challenge to FTC's liability determination.[21] The Court reiterated that the First Amendment does not protect misleading commercial speech.[22] Because FTC's finding that POM's ads were unsubstantiated was proper, and the ads did not include disclaimers sufficient to avoid being misleading, POM's ads were not protected by the First Amendment.[23]

The Court analyzed POM's challenge to FTC order's RCT requirement using the framework in Central Hudson Gas & Electric Company v. Public Services Commission.[24] Under Central Hudson, FTC's order must directly advance a substantial government interest in a manner that was not more extensive than necessary to advance that interest.[25] The Court found that the order advanced a substantial government interest by preventing misleading speech.[26] To the extent the order required a "general RCT-substantiation requirements" it was not more extensive than necessary.[27] The Court found that "[r]equiring RCT substantiation as a forward-looking remedy is perfectly commensurate" with preventing misleading speech.[28]

The Court agreed, however, with POM's First Amendment challenge to FTC's two RCT requirement. Central Hudson requires that there be "a 'reasonable fit' between the particular means chosen and the government interest pursued."[29] The D.C. Circuit concluded that FTC failed to satisfy the reasonable fit requirements because it had "inadequate justification" for its two RCT requirement for disease claims.[30] "It of course is true that, all else being equal, two RCTs would provide more reliable scientific evidence than one RCT, affording added assurance against misleading claims," the Court acknowledged. "But the Commission understandably does not claim a myopic interest in pursuing scientific certitude to the exclusion of all else, regardless of the consequences."[31] Specifically, the Court

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[21] Id. at *34.

[22] Id.

[23] Id. at *35.

[24] 447 U.S. 557, 566 (1980).

[25] POM, at *37.

[26] Id.

[27] Id. at *38.

[28] Id.

[29] Id.

[30] Id. at *3.

[31] Id.

explained that, "[i]f there is a categorical bar against claims about the disease-related benefits of a food product or dietary supplement in the absence of two [two randomized and controlled human clinical trials], consumers may be denied useful, truthful information about products with a demonstrated capacity to treat or prevent serious disease."[32]

For example, the Court posited a situation where one well-designed RCT, perhaps with other supporting non-RCT evidence, adequately substantiated a claim to the satisfaction of experts in the relevant field.[33] In support, the Court cited past guidance from the Food and Drug Administration that a single trial could provide sufficient evidence of a substance/disease relationship in certain circumstances.[34] The Court rejected FTC's argument that its precedent militated in favor of the two RCT requirement. That precedent involved a specific type of claim -- comparative efficacy claims for OTC pain relievers. In that context two RCTs could be considered appropriate, but no similar finding was present in FTC's POM order. [35] The Court also rejected FTC's other examples because they also demonstrated that FTC has imposed a two RCT requirement only in selective circumstances "based on particular concerns."[36] The order addressed FTC's concerns that POM might cherry-pick studies by requiring that POM's claims be supported by competent and reliable evidence.[37] Accordingly, the Court upheld FTC's order "to the extent it requires disease claims be substantiated by at least one RCT" but rejected it "insofar as it categorically requires two RCTs for all disease claims."[38]

The D.C. Circuit's decision confirmed that basic First Amendment principles apply to advertisements in the health space. Reinforcing Sorrell,[39] the Court stated that truthful and non-misleading speech is entitled to protection, and the speaker must provide sufficient context to ensure that the speech does not mislead the audience. Disclaimers are a less restrictive means of limiting speech than censorship. Therefore, the Court was appropriately reluctant to endorse a two RCT standard as a prerequisite for making health claims. In a statement on the decision, POM expressed appreciation "that the Court substantially reduced the requirement that FTC tried to enforce on [it] to conduct multiple double-

[32] Id. at *38.

[33] Id. at *39.

[34] Id. at *39–40.

[35] Id. at *41–42.

[36] Id. at *42–43.

[37] Id. at *44–45.

[38] Id. at *45.

[39] Sorrell v. IMS Health Inc., 131 S. Ct. 2653 (2011).

blind, placebo-controlled studies."[40] FTC's reaction will be worth monitoring in the weeks and months ahead.

More generally, the Court's First Amendment analysis may have significant implications for other areas of speech relating to FDA-regulated products. For example, the Court's analysis of Central Hudson's "reasonable fit" standard appears equally applicable to the FDA's regulation of truthful and non-misleading speech regarding conditions of use not found in approved drug and device labeling. The Court recognized that depriving consumers of "useful, truthful" information "subvert[s]" the commercial speech doctrine and signaled that categorical bars on truthful communications are unlikely to survive First Amendment scrutiny. Thus, this decision adds to the body of case law, including Sorrell and Caronia,[41] suggesting that FDA's approach to limiting dissemination of truthful speech that goes beyond the FDA-approved labeling raises serious First Amendment questions.

If you have any questions about any of the topics discussed in this advisory, please contact your Arnold & Porter attorney or any of the following attorneys:

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[40] See, e.g., "POM Wonderful loses bid to tout health benefits in drink ads," Reuters (Jan. 30, 2015), available at http://www.reuters.com/article/2015/01/30/us-pomwonderful-ftc-idUSKBN0L31TL20150130.

[41] United States v. Caronia, 703 F.3d 149 (2d Cir. 2012).